## REMARKS

The Office Action mailed May 21, 2003 has been received and reviewed. Claims 1, 3, 5, 6, 19, 20 and 23 through 25 are identified as currently pending in the Office Action. Claims 3 and 23 were withdrawn from consideration and claims 1, 5, 6, 19, 20 24 and 25 were rejected. Applicants have canceled claims 3, 20, 23 and 25, without prejudice or disclaimer and may pursue the subject matter of these claims in one or more related applications. Applicants have amended claims 1, 5, 6, 19, and 24, and presented new claims 26-28. Reconsideration of the application in view of the discussion presented herein is respectfully requested.

### 35 U.S.C. § 112, First Paragraph Rejection

Claims 1, 5, 6, 19-20 and 24-25 stand rejected in the Office Action under 35 U.S.C. § 112, first paragraph as assertedly lacking enablement. Claims 20, 23, and 25 have been canceled, rendering this rejection moot as to them. Claims 1, 5, 6, 19, and 24 are amended herein, and applicants respectfully submit that, as amended, the pending claims are enabled.

The Office Action states that:

> The specification while being enabling for the isolated full-length amino acid sequence of CD40 interacting protein, *i.e.*, TTRAP (TRAF and TNF receptor associated protein) SEQ ID NO:2, does not reasonable provide enablement for all polypeptide variants having 70-100% homology to or a fragment of SEQ ID NO:2, and a pharmaceutical composition comprising the polypeptide variant thereof, or, pharmaceutical composition comprising a compound characterized by interfering with interaction between the fragment thereof and protein factors involved in CD40-mediated signaling pathway. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. (Office Action at page 3).

Although applicants disagree with this characterization of the claims, they have amended claim independent claim 1 to facilitate allowance. Amended claim 1, now reads:

> An isolated protein characterized by an ability to form a complex with receptors of the Tumor Necrosis Factor ("TNF") superfamily including the cytoplasmic domain of CD40 as determined by a yeast two-hybrid interaction assay or a co-immunoprecipitation assay, said isolated protein comprising amino acids 54-140 of SEQ

ID NO: 2 or a fragment thereof of at least 10 amino acids in length and able to from said complex.

The Office Action asserted the claims were unenabled "as written" as they "encompass a large quantity of polypeptide fragments or variants or derivative[s]...." (Office Action at page 4). The Office action states that the language "70-100% homology ... wherein the homology *per se* is even broadened up to include any structural and functionally equivalent, e.g., genetic mutants and recombinant mutants.... Thus, the variant polypeptide molecules as claimed are far more divergent that 30% sequence identity mutants, which would render the claimed polypeptide variant highly unpredictable." (Office Action at page 4).

As amended, independent claim 1 no longer includes the language "an amino acid sequence having 70-100% homology" to the amino acid sequence of SEQ ID NO: 2. Similarly, the language defining a fragment "characterized by an ability to form a complex with receptors of the TNF superfamily including the cytoplasmic domain of CD40" has been removed. Instead, the isolated protein is defined structurally as "comprising amino acids 54-140 of SEQ ID NO: 2 or a fragment thereof of at least 10 amino acids in length." The isolated protein is then further defined functionally as "characterized by an ability to form a complex with receptors of the Tumor Necrosis Factor ("TNF") superfamily including the cytoplasmic domain of CD40 as determined by a yeast two-hybrid interaction assay or a co-immunoprecipitation assay."

The isolated protein fragment is thus defined both structurally and functionally. Support for the amendments to claim 1 may be found in the specification at Table I of Example 3, which shows that fragment 4F2d1 (amino acids 54-140 of SEQ ID NO: 2, see specification at page 12, line 13) binds with CD40, at Example 6 and Example 7, which in connection with Example 3 support the language "as determined by a yeast two-hybrid interaction assay or a co-immunoprecipitation assay," and at page 15, lines 5-6 of the specification (for the language "at least 10 amino acids in length").

Applicants respectfully submit that, as amended, claim 1 is fully supported and enabled by the present specification. It is requested that amended claim 1, with claims , 5, 6, 19, 24 and 26-28 dependent therefrom, be allowed.

**35 U.S.C. § 102(b) Anticipation Rejections**

*Anticipation Rejection Based on Green et al.*

Claims 1 and 19 stand rejected in the Office Action under 35 U.S.C. § 102(b) as assertedly anticipated by Green C.B. et al. *Proc. Natl. Acad. Sci.* USA (1996) 93, 14884-14888, (hereinafter "Green"). Applicants respectfully submit that, as amended, claim 1 and claim 19 each define over Green, as hereinafter set forth.

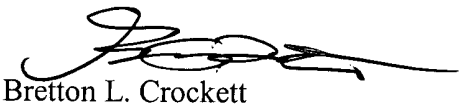
A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The Office Action states that "[t]he nocturin polypeptide comprises an amino acid fragment (residues 347-351) homologous to the fragment (residues 347-351 of SEQ ID NO:2 of the current disclosure, which meets the limitation of 'or a fragment thereof said protein...' set forth in [claim 1]...." As amended, claim 1 now includes the elements of "said isolated protein comprising amino acids 54-140 of SEQ ID NO: 2 or a fragment thereof of at least 10 amino acids in length." Claim 19 similarly includes these elements, as it depends from claim 1, and has been further amended for clarification. Applicants respectfully submit that the 5 amino acid fragment of Green fails to disclose the claimed elements. Accordingly, it is requested this rejection be withdrawn and the claims allowed.

## Conclusion

All pending claims are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Office determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,



Bretton L. Crockett
Registration No. 44,632
Attorney for Applicants
TRASKBRITT
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

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